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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/726,193	11/29/2000	Chih-Ming Chen	300.1023	6199
23280	7590	11/04/2005		
DAVIDSON, DAVIDSON & KAPPEL, LLC 485 SEVENTH AVENUE, 14TH FLOOR NEW YORK, NY 10018				
			EXAMINER FUBARA, BLESSING M	
			ART UNIT	PAPER NUMBER
			1618	

DATE MAILED: 11/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/726,193	CHEN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Blessing M. Fubara	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 10 August 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,4,6,8-20,24-33 and 35-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4,6,8-20,24-33 and 35-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

Examiner acknowledges receipt of Appeal Brief and request for extension of time filed 08/10/05 and Notice of Appeal filed 04/08/05. Claims 1, 4, 6, 8-20, 24-33 and 35-39 are pending.

Upon further consideration of the arguments in the Appeal Brief, the finality of the Office action is withdrawn in favor of the rejection below.

The rejection of claims 1, 4, 6, 8-20 and 24-32 as being anticipated by Scott (US 3,621,097) under 35 USC 102(b) was withdrawn in the advisory action.

#### ***Claim Rejections - 35 USC § 102***

1. The rejection of claims 1, 4, 6, 8-20 and 24-32 under 35 U.S.C. 102(b) as being anticipated by Barry et al. (US 5,055,306) is withdrawn because while Barry discloses a composition that contains metformin, Barry does not disclose an example of a formulation containing metformin.

However, Barry renders the claims obvious as discussed below.

#### ***Claim Rejections - 35 USC § 103***

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1, 4, 6, 8-20, 24-33 and 35-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barry et al. (US 5,055,306).

Barry discloses sustained release formulation (abstract; column 3, lines 37-41) and a class of drugs that can be formulated as the sustained release dosage of Barry is the class of drugs used

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in diabetes and metformin and tolbutamide are the only antidiabetic agents listed (column 7, lines 36).

The instant claims are directed to sustained release formulation comprising metformin as the sole active agent. The claims then describe the function of the formulation. No specific dosage is claimed. No specific polymers are claimed.

Thus the disclosure of a sustained release formulation where the antidiabetic agents metformin and tolbutamide can be active agents meets the limitation of the broad claim to sustained release formulation where the active agent is metformin, therefore, the broad claim to sustained release metformin formulation reads on the disclosure of Barry. With respect to the function or property of the metformin formulation, it is noted as stated in MPEP 2112.02 [R-2] II, "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990)."

Therefore, administration of product/composition that is essentially the same as the claimed formulation would exhibit the properties/functions recited in the pending claims. Absent a showing of factual evidence, the metformin formulation of Barry would have the properties and functions recited in the instant claims.

Although there is no exemplification of the metformin or tolbutamide formulation, there is a disclosure of a sustained release formulation where metformin and tolbutamide are the suggested antidiabetic agents. The list for antidiabetic agents is not exhaustive.

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Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a sustained release formulation. One having ordinary skill in the art would have been motivated to prepare the sustained release formulation dosage forms that are specifically exemplified and those that may not be exemplified if the goal is to formulate any of those that are not exemplified bearing in mind that the prior art cannot exemplify all the possible drugs that can be formulated as such. One having ordinary skill in the art would have been motivated to use tolbutamide or metformin if the desired active agent is an antidiabetic agent with the expectation that the release of metformin or tolbutamide from the formulation would be sustained. The release of metformin or tolbutamide from the formulation of Barry would be sustained absent a factual evidence to the contrary. MPEP 2112.01 [R-2] I states, "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). *"When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not."* In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). *Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433."*

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

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Pentikainem (in International Journal of Clinical Pharmacology, Therapy and Toxicology, Vol. 24, No. 4, 1986, pp. 213-220) discloses studies comparing sustained release products of metformin (D, C, E0 with rapidly dissolving tablet (B) and aqueous solution (A).

McCarty et al. (US 5,914,326) discloses sustained release metformin formulation (column 4, lines 21, 43 and 44, claims 7, 14 and 16).

Applicants argue that Barry provides a laundry list of agents of which metformin is one and for which there is no exemplification, no teaching of structural similarity, and that the tablet is not swallowed whole.

#### *Response to Arguments*

5. Applicants' arguments filed 08/10/05 have been fully considered but they are not persuasive.

A. Size of genus not sufficiently small – laundry list

The size of the genus is specifically small when the reference is made to antidiabetic agent. Even then, the list considered as a whole does not appear to be exhaustive.

B. No teaching of structural similarity

The instant claims broadly direct the formulation to a sustained release formulation of metformin without recitation of specific dosage forms or sustained release polymers. In this wise, the composition/product of the prior art are structurally or compositionally similar.

C. No Exemplification of metformin formulation

MPEP 608.01(b) [R-2] B states “exemplification of a species could be illustrative of members of the class. For processes, the type reaction, reagents and process conditions should be stated, generally illustrated by a single example unless variations are necessary.” In this case Barry

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discloses sustained release formulation where a variety of drugs can be formulated into the sustained release formulation. Each composition containing a specific listed drug represents a species and all specie formulation need not be illustrated by an example.

D. Tablet is not swallowed whole

With respect to this argument, it is noted that, the formulation is sustained and there is no factual evidence the formulation of Barry would not be sustained when not swallowed whole.


***"When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433."***


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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